REMARKS

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

I. CLAIM STATUS AND AMENDMENTS

Claims 1, 3-6, 8, 9 and 11-25 were pending in this application when last examined.

Claims 1, 3-6, 8, 9, 11-13, 24 and 25 were examined on the merits and rejected.

Claims 14-23 were withdrawn as non-elected subject matter.

Claim 1 is amended to delete "further" in line 4 before "comprises." Support can be found in the claim as filed.

No new matter has been added.

II. INDEFINITENESS REJECTION

On page 2 of the Office Action, claims 1, 3-6, 8, 9, 11-13 and 24-25 were rejected under 35 U.S.C. § 112, second paragraph as indefinite for the phrase "further" in the last line of claim 1.

It is respectfully submitted that the present amendment overcomes this rejection for reasons which are self-evident.

III. ANTICIPATION REJECTION

On pages 2-4 of the Office Action, claims 1, 3-6, 8, 9, 11-13 and 24-25 remain rejected under 35 U.S.C. § 102(b) as anticipated by Ried et al. (US 5,919,624).

This rejection is respectfully traversed as applied to the amended claim.

Amended claim 1 requires the tissue section to be "rinsed with a culture medium". As noted in the response filed December 8, 2005, the limitation "rinsed with a culture medium" is sufficient to "pre-balance" the tissue section with a culture medium, because after the rinsing step the culture medium remains in the tissue section. This makes the rinsed tissue section easy to

handle for cell culture. In fact, amended claim 1 clearly requires that the tissue section "comprises the culture medium" after the rinsing.

Again, it is respectfully submitted that the tissue section in Ried does <u>not</u> contain a culture medium. The tissue sections in Ried are <u>not</u> in contact with a culture medium.

Consequently, the tissue section in Ried does <u>not</u> contain the culture medium. As a result, the tissue section in Reid does not have the property of being easy to handle for cell culture, which is a property of the present invention. Therefore, Ried fails to disclose each and every element in the claimed invention, which is a requirement for anticipation.

In reply, at page 7 of the Action, the Office argued that "paraffin" as used in Ried is a "culture medium" within the broadest sense of the term.

This position is respectfully traversed.

It is recognized in the art field that "paraffin" is <u>not</u> a "culture medium" as evidenced by the attached online-dictionary definitions of these terms.

"Culture medium" is generally defined as a liquid or gelatinous substance containing nutrients in which microorganisms or tissues are cultivated for scientific purposes.

"Paraffin" is generally defined as a waxy white or colorless solid hydrocarbon mixture used to make candles, wax paper, lubricants, and sealing materials. While paraffin is often used for <u>fixing</u> in order to form tissue sections, it is <u>not</u> a "culture medium"

Based on such definitions, it is clear that the art field recognizes the "paraffin" is not a "culture medium". They are not equivalent terms. Therefore, the Office's characterization of "paraffin" contrasts with its recognized meaning. The Office is respectfully requested to point to the support in the cited references or in the art field that "paraffin" as used in Ried is a "culture medium"

In view of the above, it is again respectfully submitted that Ried fails to teach each and every limitation. Therefore, the rejection of claims 1, 3-6, 8, 9, 11-13 and 24-25 under 35 U.S.C. § 102(b) is untenable and should be withdrawn.

IV. OBVIOUSNESS REJECTION

On pages 4-6 of the Office Action, claims 1, 3-6, 8, 9, 11-13 and 24-25 remain rejected under 35 U.S.C. § 103(a) as obvious over Badylak et al. (WO 99/12555) and Mori et al. (Anat. Embryol., Vol. 199, pp. 319-327, 1999) taken with Ried et al. (US 5,919,624) and Sitte (US 3,785,234).

This rejection is respectfully traversed as applied to the amended claims.

Again, claim 1 requires that the tissue section be rinsed with a culture medium and comprises the culture medium. It is respectfully submitted that the cited prior art references fail to disclose or suggest this element of the claimed invention. For this reason alone, the cited references do not render obvious the claimed invention.

In addition, it is respectfully submitted that the combined teachings of the cited references would not motivate one of ordinary skill in the art to prepare an animal-derived or plant-derived tissue section-containing carrier according to the claimed invention.

In particular, as noted in the last response, WO 99/12555 is directed to the use of submucosal tissue which is enzymatically treated with galactosidase which can be implanted to replace or support damaged or diseased tissues or to form a cell culture growth substrate. The submucosal tissue has a thickness of about 100 to 200 μ m and consists primarily of acellular, extracellular matrix material. See the Abstract and page 4, lines 30-32.

There is no suggestion in the reference that other tissue sections from animals or plants may be used as a cell culture growth substrate, nor that the cell culture substrate may have a thickness of from 0.5 to 50 μ m.

There is also no suggestion of a rinsing step with a culture medium, such that a culture medium remains in the tissue section.

Mori also fails to disclose or suggest the use of an animal-derived or plant-derived tissue section in a thickness of 0.5 to 50 μ m used as a substrate for seeding and culturing animal cells. Instead, Mori describes cutting neonatal mouse liver tissues into 250 μ m slices and culturing the tissue to maintain the parenchymal cells and ontogenesis and to investigate their proliferation and

differentiation. There is no teaching or suggestion of using the tissue section as a cell culture substrate.

The Ried patent is directed to methods of detecting the presence of cervical carcinoma by examining tissue sections. There is no teaching or suggestion of using the tissue section as a cell culture growth substrate.

The Sitte patent is directed to devices for cutting thin tissue sections.

No where in the combined teachings of the cited references is there a suggestion for a tissue section-containing carrier derived from animal or plant, for seeding and culturing animal cells, wherein the tissue section having thickness of 0.5 to 50 μ m is adhered to a support and rinsed with a culture medium and further comprises the culture medium.

In response to the above arguments, the Office argued that it would have been obvious to optimize or modify the thickness of the tissue section to obtain a thickness of 0.5 to 50 μ m.

However, a thickness of 100 to 200 μ m in WO 99/12555 and a thickness of 250 μ m in Mori are no where close to suggesting a thickness of 0.5 to 50 μ m as in the present invention. Given the huge discrepancies in the thickness, it would seem that the claimed thickness of 0.5 to 50 μ m would not be routinely optimized as suggested by the Office. In fact, it could be said that the art actually teaches away from using the claimed thickness of 0.5 to 50 μ m.

In view of the above, the rejection of claims 1, 3-6, 8, 9, 11-13 and 24-25 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

Respectfully submitted,

Toshiaki TAKEZAWA et al.

Jone Williams

Registration No. 48,036 Attorney for Applicants

JFW/akl Washington, D.C. 20006-1021 Telephone (202) 721-8200 Facsimile (202) 721-8250 August 31, 2006

Attorney Docket No. 2001_1784A Serial No. 09/980,246 <u>August 31, 2006</u>

ATTACHMENTS

1. online dictionary definitions of the terms "culture medium" and "paraffin"

American Heritage Dictionary - Cite This Source new!

culture medium

n.

A liquid or gelatinous substance containing nutrients in microorganisms or tissues are cultivated for scientific purposes.

The American Heritage® Dictionary of the English Language: Fourth Edition. 2000.

paraffin

SYLLABICATION: par·af·fin

PRONUNCIATION: Spar's-fin

NOUN: 1. A waxy white or colorless solid hydrocarbon mixture used to make

candles, wax paper, lubricants, and sealing materials. Also called <u>paraffin wax</u>. 2. Chemistry A member of the alkane series. 3. Chiefly

British Kerosene.

TRANSITIVE Inflected forms: par-af-fined, par-af-fin-ing, par-af-fins

VERB: To saturate, impregnate, or coat with paraffin.

ETYMOLOGY: German: Latin parum, little, not very; see pau-1 in Appendix I + Latin

affinis, associated with (from its lack of affinity with other materials);

see affined.

OTHER FORMS: par'af-fin'ic —ADJECTIVE

The American Heritage[®] Dictionary of the English Language, Fourth Edition. Copyright © 2000 by Houghton Mifflin Company. Published by t Houghton Mifflin Company. All rights reserved.

paraffin

2 entries found for **paraffin**. To select an entry, click on it.

paraffin Go alkane

Main Entry: par·af·fin •

Pronunciation: 'per-&-f&n, 'pa-r&-

Function: noun

Etymology: German, from Latin parum too little (akin to Greek pauros little, paid-, pais child) + affinis bordering on --

more at FEW, AFFINITY

1 a: a waxy crystalline flammable substance obtained especially from distillates of wood, coal, petroleum, or shale oil that is a complex mixture of hydrocarbons and is used chiefly in coating and sealing, in candles, in rubber compounding, and in pharmaceuticals and cosmetics b: any of various mixtures of similar hydrocarbons including mixtures that are semisolid or oily

2: ALKANE

3 chiefly British: KEROSENE

- par·af·fin·ic 4) /"per-&-'fi-nik